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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,277	03/23/2001	Gholam A. Peyman	41441	4578

1609 7590 12/15/2003

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EXAMINER

SHAY, DAVID M

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on September 5, 2003

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15, 17-21, 23, 24, + 26-35 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-15, 17-21, 23, 24, + 26-35 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 9, 10, 12, 13, 21, 23, 26, 27, 33, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 27, it is unclear what further structure of the laser is to be inferred by reciting the particular portion of the corneal surface the laser is to act on. Claims 9, 10, 12, 13, 21, 23, 33 and 34 merely recite the use of a particular structure, thus what further manipulative aspect of the method is intended to be specified is unclear.

Claims 1-4, 7-13, 17-19, 31, 34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al ('586) in combination with Neefe and Simon. Bille et al ('586) teach a method of forming a pocket in the stroma using an ultrashort pulse laser. Simon teaches forming an intrastromal pocket and inserting a gel which is then allowed to set and can then be adjusted. Neefe teaches adjusting corneal curvature using a mold. It would have been obvious to the artisan of ordinary skill to employ the laser method of Bille et al ('586) in the method of Simon, since this could form the intrastromal pocket much more precisely than the mechanical device of Simon and will not accidentally perforate the lamellae; or to employ the implant method of Simon in the method of Bille et al ('586), since this would provide an adjustable correction, as taught by Simon, and to irradiate the gel to expand or contract the gel, since this would enable adjustment of astigmatism, and to set the gel chemically since this is equivalent to cross linking by irradiation and provides no unexpected result; to employ a mold in the method of Bille et al ('586) or Simon since this would be more precise and less cumbersome than the

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manual massage method of Simon for removing excess gel; and to form the pocket about one third the distance from the surface, since this is not critical and provides no unexpected result thus producing a method such as claimed.

Claims 1, 4-6, 14, 15, and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al ('586) in combination with Neefe, L'Esperance, Jr. ('913) and Simon. Bille et al ('586) teach a method of forming a pocket in the stroma using an ultrashort pulse laser. Simon teaches forming an intrastromal pocket and inserting a gel which is then allowed to set and can then be adjusted. Neefe teaches adjusting corneal curvature using a mold. L'Esperance, Jr. ('913) teaches ablating the corneal surface with an excimer laser to provide optical correction. It would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al in the method of Simon, since this could form the intrastromal pocket much more precisely than the mechanical device of Simon and will not accidentally perforate the lamellae; or to employ the implant of Simon in the method of Bille et al ('586), since this would provide an adjustable correction, as taught by Simon, and to irradiate the corneal surface with an excimer laser, as taught by L'Esperance ('913), since this would enable adjustment of astigmatism, and to employ a mold in the method of Bille et al ('586) or Simon for since this would be more precise and less cumbersome than the manual message method of Simon for removing excess gel thus producing a method such as claimed.

Claims 20, 21, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al ('586) in combination with L'Esperance, Jr. ('913) and Simon. Bille et al teach a method of forming a pocket in the stroma using an ultrashort pulse laser. Simon teaches forming an intrastromal pocket and inserting a gel which is then allowed to set and can then be adjusted.

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L'Esperance, Jr. ('913) teaches adjusting corneal curvature using an excimer laser. It would have been obvious to the artisan of ordinary skill to employ the laser of Bille et al ('586) in the method of Simon, since this could form the intrastromal pocket much more precisely than the mechanical device of Simon and will not accidentally perforate the lamellae; or to employ the implant of Simon in the method of Bille et al ('586), since this would provide an adjustable correction, as taught by Simon, and to irradiate the corneal surface with an excimer laser, as taught by L'Esperance ('913), since this would enable adjustment of astigmatism, thus producing a method such as claimed.

Claims 24 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al ('586) in combination with Simon and L'Esperance, Jr. ('913). The teachings of L'Esperance, Jr. ('913), Simon, and Bille et al ('586) are substantially as set forth above. It would have been obvious to the artisan of ordinary skill to assemble these elements into a kit, since this would enable the performance of the obvious method as set forth above and because the elements are functionally unrelated as claimed; and to form the optical element as a ring, since this is not critical and is the desired configuration of Simon, thus producing a kit such as claimed.

Applicant's arguments have been fully reviewed, but are not convincing. Applicant argues that functional language does not in and of itself indefinite, citing MPEP 2173.05 (g). While this is noted, the examiner submits that applicant's reliance on section 2173.05(g) is misplaced. Reviewing the example set forth in that section, it is clear that "adapted to" language can be proper in the context of a claim for a kit serve to define structural attribute of interrelated component parts. However, as the "adapted" language only refers to the cornea, this could only

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be construed as a limitation if the cornea itself were considered a recited element of the kit, in which case, as applicant is no doubt aware, a rejection under 35 USC 101 would be necessitated. Thus the examiner must regard the language as non-limiting. If applicant intends to include the cornea itself as part of the kit, he is required to specifically so state on the record, that, if proper, a rejection under 35 USC 101 may be applied.

Regarding claims 9, 10, 12, 13, 33, and 34 applicant argues that the claims clearly further define the step by limiting how to perform the step. However, as no specific manipulation is recited in the claim, nor taught in the specification regarding the insertion of a lens, or use of one particular laser as opposed to a generic laser. Thus these arguments too are not convincing.

Regarding the art rejections, applicants arguments appears to hinge on applicants assertion that Neeffe does not teach reshaping ocular material and that Neeffe discloses reshaping the corneal surface and not the material there under. With respect to applicants first assertion this is clearly erroneous. Neeffe teaches reshaping the cornea, which is composed of collagen. Attention is respectfully invited to page 7 of the instant disclosure as originally filed, line 13 thereof reads, in pertinent part "the ocular material can be collagen combined with or without cells;" With respect to the second assertion, applicant has put forth no credible rationale which would allow the surfaces of the cornea (i.e. the top layer of cells in the epithelium only) to be reshaped with all subsurface material remaining in its original shape. But regardless of this, Neeffe does discuss reshaping the stroma (see e.g. column 1, lines 61-62). Thus this argument is not well founded.

Applicant makes, with respect to claim 20 its dependents, applicant argues that the combination does not teach using a laser to produce as Simon does a ring shaped pocket offset

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from the main optical axis, and using a leaser to ablate the overlying portion of the first surface. The examiner must respectfully disagree. Bille et al ('586) teach that the tissue can be removed in a variety of configurations, as applicant has pointed to no passage or structure in Bille et al ('586) nor has the examiner found any that would indicate that the method could not be used to produce the incision of Simon, the mere statement on applicants part that Bille et al ('586) could not produce the pocket of Simon is not convincing.

Applicant's arguments filed September 5, 2003 have been fully considered but they are not persuasive.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.



Shay/DI

November 21, 2003

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330